

# camurus®

INTERIM REPORT FOR  
THE FIRST QUARTER 2019

“Initial sales of Buvidal® follows plan and we are expecting to see significant growth during the year”

## **camurus.**

Camurus is committed to developing and commercializing innovative and long-acting medicines for the treatment of severe and chronic conditions, including opioid dependence, pain, cancer and endocrine disorders. New drug products are based on our proprietary FluidCrystal® technologies with the purpose to deliver improved quality of life, treatment outcomes and resource utilization. The company's share is listed on Nasdaq Stockholm under the ticker "CAMX". For more information, visit [camurus.com](http://camurus.com)

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## FIRST QUARTER SUMMARY

- Buvidal® launched as the first long-acting medicine for opioid dependence in the EU; with initial sales in Finland, the UK, Sweden, Germany and Denmark
- Net revenues amounted to MSEK 18.5 (14.6), of which MSEK 11.0 (3.0) were from product sales
- Enrollment completed in the DEBUT clinical study, comparing Buvidal® with daily treatment with sublingual buprenorphine/naloxone
- Last patient last visit in the Phase 3 long-term extension study of CAM2038 for treatment of chronic pain
- Phase 3 study protocol for CAM2029 in acromegaly finalized after alignment with the US FDA
- Completed rights issue of MSEK 403

## SIGNIFICANT EVENTS AFTER THE PERIOD

- Camurus’ partner Braeburn initiated court proceedings to overturn a market exclusivity extending to 30 November 2020 and seek immediate market approval of Brixadi™ (the US trade name for Buvidal®) for the treatment of opioid use disorder in the US

## OUTLOOK FOR 2019

- Net revenues are expected to be in the region of MSEK 130–160\*, with product sales of MSEK 70–90

\* Forecast does not include possible milestone payments relating to Brixadi™ in the US

## FINANCIAL SUMMARY

| MSEK                                             | 2019<br>Jan-Mar | 2018<br>Jan-Mar | 2018<br>Jan-Dec |
|--------------------------------------------------|-----------------|-----------------|-----------------|
| Net Revenue                                      | 18.5            | 14.6            | 49.3            |
| – Whereof product sales                          | 11.0            | 3.0             | 11.3            |
| Operating result                                 | -84.4           | -46.4           | -287.2          |
| Result for the period                            | -67.6           | -36.3           | -234.7          |
| Earnings per share SEK before and after dilution | -1.50           | -0.97           | -6.20           |
| Cash position                                    | 406.6           | 266.6           | 134.4           |

## FINANCIAL CALENDAR 2019

|                             |                      |
|-----------------------------|----------------------|
| Presentation Q1 2019        | 9 May 2019, 2 pm CET |
| Annual General Meeting 2019 | 9 May 2019           |
| Q2 report 2019              | 18 July 2019         |
| Q3 report 2019              | 8 November 2019      |

## INVESTOR CONFERENCE CALL, ANALYSTS AND MEDIA

Q1 report for 2019 and an operational update will be presented by CEO Fredrik Tiberg and members of the Camurus management team on Thursday 9 May 2019, at 2 pm (CET). The conference call can also be followed by a link on the website, [camurus.com](http://camurus.com)

External link:  
<https://financialhearings.com/event/12052>

# Positive market signals for Buvidal® in Europe

During the first quarter of 2019, we initiated the European launch of Buvidal®, our in-house developed, weekly and monthly depots for the treatment of opioid dependence. In our first launch market, Finland, an estimated 6% of patients with opioid dependence are receiving Buvidal® after its first 3 months of availability. Subsequently, we have launched Buvidal® in the UK, Sweden, Germany and Denmark, with a considerable interest in all markets and a positive response from healthcare providers and patients.

## **POSITIVE START OF EU LAUNCH**

Following the launch of Buvidal®, patients in the EU have access to the first innovative long-acting medication for the treatment of opioid dependence, with individualized flexible weekly and monthly dosing. So far, around 500 patients have initiated treatment with Buvidal®, including new-to-treatment patients, and patients transferring from daily medication with sublingual buprenorphine and methadone. The majority of these patients are from Finland and Germany, while initial patient uptake in the UK, Sweden and Denmark, has, as

expected, been less rapid due to the reimbursement and formulary listing processes. In Norway and Australia, we have submitted pricing and reimbursement applications and are expecting positive decisions and aim to start launches shortly thereafter. Initial sales of Buvidal® follows plan and with the positive feedback and engagement with stakeholders we are expecting to see significant growth during the year.

## **LARGE INTEREST IN BUVIDAL® IN THE CRIMINAL JUSTICE SETTING**

Aside from very positive signals from healthcare providers, we have also seen a significant interest in our long-acting treatment solutions for use in custodial settings, where the unmet medical need of a safe and effective treatment alternative is significant. Several prisons in Germany have recently begun using Buvidal® for the treatment of patients with opioid dependence, with the expectation that our long-acting treatments will lead to improvement of outcomes and significant treatment efficiencies. Additionally, treatment with weekly and monthly Buvidal® may facilitate the transition to outpatient treatment protecting patients from the known risks of overdose and death during the first weeks of being released from prison. To further the understanding of the contribution Buvidal® can make in custodial settings a clinical UNLOC-T study comparing Buvidal® with methadone at eight prisons in New South Wales, Australia, is also progressing and initial results are expected in the fourth quarter of 2019. With a



large unmet need and more than 100,000 individuals with opioid dependence in the EU and Australian prison systems combined, we see significant opportunities for Buvidal® in the criminal justice setting.

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**“Around 500 patients have initiated treatment with Buvidal®”**

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In the first quarter of 2019 we completed enrollment in the DEBUT outpatient clinical study comparing Buvidal® with daily standard-of-care with sublingual buprenorphine/naloxone. Results are expected during the fourth quarter.

A detailed subgroup analysis of fentanyl users in the pivotal Phase 3 study of Buvidal® compared to sublingual buprenorphine/naloxone was also conducted. The results, showing improved outcomes and less illicit opioid use in

patients treated with Buvidal®, were presented by Professor Edward Nunes, Columbia Medical School at the American Society of Addiction Medicine 50th Annual Meeting in Orlando, and generated significant interest.

#### **COURT PROCEEDINGS INITIATED IN THE US**

After the first quarter, our partner Braeburn filed an action in federal district court for the District of Columbia, seeking to overturn the market exclusivity extending to 30 November 2020 granted by the US Food and Drug Administration (FDA) to Sublocade™, and seeking immediate approval of Brixadi™. A court decision is expected during the third quarter of 2019.

#### **CONTINUED INVESTMENT IN THE PRODUCT PIPELINE**

The last patients in the 52-week Phase 3 long-term safety extension study of CAM2038 in patients with chronic pain completed their treatment during the first quarter of 2019. After closing of the database and compiling of results and the study report, we will meet with European regulatory authorities to discuss the regulatory submission for CAM2038 for the treatment of chronic pain. We plan to submit in the EU during the first half of 2020.

Another important milestone for us is the start of the Phase 3 program for our subcutaneous octreotide, CAM2029, being developed for the treatment of acromegaly and neuroendocrine tumors (NET). CAM2029 has been designed for easy self-administration and optimization of treatment effects for these chronic diseases. During the first quarter, we initiated

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**”Our key objective for 2019 is to give patients in Europe and Australia rapid access to treatment with Buvidal®”**

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manufacturing and finalized the pivotal Phase 3 study protocol after alignment of study details with the FDA. Clinical trial applications are submitted in the US and a number of national regulatory authorities in Europe. The goal is to start treatment in the Phase 3 study of CAM2029 at the beginning of the third quarter of 2019.

We also continued to work on the development of a Phase 2 study of CAM2043 (treprostinil), for the treatment of pulmonary arterial hypertension (PAH) and systemic sclerosis and aim to initiate Phase 2 clinical trials in patients towards the end of the year. Additionally, activities continued in other internal projects as well as in our partnerships, including with Braeburn, Rhythm and Solasia.

To secure financing of prioritized development projects and for the launch of Buvidal® in Europe and Australia, we completed a rights issue of SEK 403 million before issue costs towards the end of the quarter.

#### **FOCUS ON LAUNCHES AND GROWTH**

Our key objective for 2019 is to give patients in Europe and Australia rapid access to treatment with Buvidal®. Based on the high unmet medical need in opioid dependence and the positive feedback on treatment with Buvidal® from both patients and healthcare providers, we expect to see significant sales and growth over the year. This ambition is supported by a strong commercial organization with fully operational regional teams in Germany, the UK, the Nordics and Australia, and with local presence in France, Spain and Italy.





With the significant opportunity presented by Buvidal® in opioid dependence, alongside expected development milestones in our pipeline of innovative products and our partnerships, I believe the 2019 outlook for Camurus is optimistic and will enable us to deliver strong growth and value for patients and shareholders.

*Fredrik Tiberg, President & CEO*

# Broad and diversified pipeline

Camurus is a research-based pharmaceutical company with a focus on the development and commercialization of new and innovative pharmaceuticals for serious and chronic conditions, where there are clear medical needs and the potential to significantly improve treatment. For the development of new drug candidates Camurus utilizes its own proprietary formulation technology, such as the long-acting injection depot FluidCrystal®. New proprietary medicines with improved properties and treatment outcomes are develop-

ped by combining the company's patented drug delivery technologies with active ingredients with documented safety and efficacy profiles. These are developed with significantly lower cost and risk, compared with the development of completely new pharmaceuticals. Camurus' development pipeline contains product candidates for the treatment of cancer and the side effects of cancer treatment, endocrine diseases, pain and addiction. A summary and status update on the different projects is given below.

| PRODUCT                                                                                                                                                                                                                       | PHASE 1-2 | PHASE 3 | REGISTRATION         | MARKET                                                                                       |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|---------|----------------------|----------------------------------------------------------------------------------------------|
| Buvidal® q1w OPIOID DEPENDENCE                                                                                                                                                                                                |           |         |                      | APPROVED  |
| Buvidal® q4w OPIOID DEPENDENCE                                                                                                                                                                                                |           |         |                      | APPROVED  |
| Brixadi™ q1w OPIOID DEPENDENCE <sup>1</sup>                                                                                                                                                                                   |           |         | TENTATIVELY APPROVED |           |
| Brixadi™ q4w OPIOID DEPENDENCE <sup>1</sup>                                                                                                                                                                                   |           |         | TENTATIVELY APPROVED |           |
| CAM2038 q1w CHRONIC PAIN <sup>1</sup>                                                                                                                                                                                         |           | PHASE 3 |                      |                                                                                              |
| CAM2038 q4w CHRONIC PAIN <sup>1</sup>                                                                                                                                                                                         |           | PHASE 3 |                      |                                                                                              |
| CAM2029 ACROMEGALY                                                                                                                                                                                                            | PHASE 1-2 |         |                      |                                                                                              |
| CAM2029 NEUROENDOCRINE TUMORS                                                                                                                                                                                                 | PHASE 1-2 |         |                      |                                                                                              |
| CAM2032 PROSTATE CANCER                                                                                                                                                                                                       | PHASE 1-2 |         |                      |                                                                                              |
| CAM4072 GENETIC OBESITY DISORDERS <sup>2</sup>                                                                                                                                                                                | PHASE 1-2 |         |                      |                                                                                              |
| CAM2043 PULMONARY ARTERIAL HYPERTENSION                                                                                                                                                                                       | PHASE 1-2 |         |                      |                                                                                              |
| CAM2047 CHEMOTHERAPY INDUCED NAUSEA & VOMITING                                                                                                                                                                                | PHASE 1-2 |         |                      |                                                                                              |
| CAM2048/2058 POSTOPERATIVE PAIN & PONV <sup>1,3</sup>                                                                                                                                                                         | PHASE 1-2 |         |                      |                                                                                              |
| <p>1) Braeburn holds the rights to North America.<br/>                 2) Developed by Rhythm Pharmaceuticals under a worldwide license to FluidCrystal®<br/>                 3) PONV: Postoperative nausea and vomiting.</p> |           |         |                      |                                                                                              |
| <b>MEDICAL DEVICE</b>                                                                                                                                                                                                         |           |         |                      |                                                                                              |
| episil® oral liquid ORAL MUCOSITIS                                                                                                                                                                                            |           |         |                      | MARKET                                                                                       |



### **Buvidal® – opioid dependence**

Opioid dependence is a serious, chronic, relapsing disease and a growing global health problem. Medication assisted treatment (MAT) with daily buprenorphine and methadone is the current standard of care, effectively reducing withdrawal and cravings, misuse and spread of diseases. However, these treatments are also associated with limitations such as poor treatment adherence, misuse, medication diversion, and accidental pediatric exposure.

Buvidal® (CAM2038) weekly or monthly subcutaneous injectable formulation of buprenorphine is developed to promote compliance and eliminate the risk of abuse and diversion compared to current daily treatments. Buvidal® is the first long-acting injectable for treatment of opioid dependence that is approved in EU and Australia. It gives healthcare providers the possibility to individualize treatment according to the patient's needs and is designed to mirror the dosing regimen of daily buprenorphine, allowing for direct transition from daily buprenorphine therapy. Buvidal® relieves the patient from the daily reminder and burden of the disease and allows the healthcare provider to focus on treating the disease and counseling the patient rather than policing medical compliance. Buvidal® may promote greater patient adherence and compliance, thereby reducing costs for supervision and the risks of relapse, overdose and death.

Buvidal® has been studied in a comprehensive clinical program comprising seven clinical studies, including two Phase 3 studies. A pivotal efficacy study met both the FDA and EMA primary efficacy endpoints (responder rate and mean percentage of urine samples negative for illicit opioids). In addition, superiority of Buvidal® was demonstrated for the cumulative percentage of patients with no evidence of illicit opioid use during treatment weeks 4 to 24. The safety profile of Buvidal® was generally consistent with the known safety profile of buprenorphine except for mild-to-moderate

injection-site adverse events. The results of clinical trials have been presented at several international scientific/clinical meetings as well as published in well-renowned international scientific/medical journals.

In November 2018, Camurus received EU approval for weekly and monthly Buvidal® for the treatment of opioid dependence in adults and adolescents aged 16 years or over. Later in the month, Buvidal® Weekly and Buvidal® Monthly depots were also approved in Australia by the Australian Therapeutic Goods Administration (TGA) for maintenance treatment of opioid dependence within a framework of medical, social and psychosocial support. In December 2018, the FDA issued a tentative approval of Brixadi™ (the US trade name for Buvidal®). With the tentative approval, Brixadi™ has met all regulatory standards of clinical and non-clinical safety, efficacy and quality for US approval. However, final approval of a monthly depot is according to the FDA subject to the expiration of an exclusivity period granted to Sublocade™ until 30 November 2020.

#### **STATUS Q1**

During the quarter, Buvidal® was launched in Finland, Sweden, Germany and the UK. So far, about five hundred patients have initiated treatment, and the feedback from patients and physicians has been very positive. Focus is now on enabling patient access by having Buvidal® included in treatment plans, guidelines and formularies, and by working to secure reimbursement and the availability of appropriate resources for opioid dependence treatment at regional and national levels.

After the period, in April 2019, Camurus' partner Braeburn initiated court proceedings to overturn a market exclusivity extending to 30 November 2020 and seek immediate market approval of Brixadi™ for the treatment of opioid use disorder in the US. A court decision is expected during the third quarter of 2019.

In Israel, Camurus' distribution partner Medison Pharma is currently compiling the application of marketing approval for Buvidal® in opioid dependence. Product launch in Israel is planned for Q1 2020.

### **CAM2038 – chronic pain**

Chronic pain is a global health problem, causing deterioration in general health, reduced quality of life, decreased work capacity and dependence and misuse of strong opioids. CAM2038 is being developed to provide round-the-clock pain relief, while decreasing the risk of respiratory depression and fatal overdoses associated with full  $\mu$ -opioid agonists, such as morphine, oxycodone and fentanyl. With CAM2038 we aim to provide the combination of long-lasting efficacious analgesia with the reduced risk of misuse, abuse and illicit diversion.

CAM2038 has been successfully evaluated in a randomized Phase 3 efficacy study in opioid experienced patients with chronic low-back pain. The study met its primary and first secondary endpoints by demonstrating that treatment with CAM2038 resulted in significantly improved relief of the average and worst pain intensity compared to placebo. The additional secondary endpoints were supportive of the main results.

#### **STATUS Q1**

Following completion of the randomized efficacy part of the Phase 3 study, the long-term safety of CAM2038 is being evaluated in a 52-week open label extension study, in roll-over patients with chronic low-back pain from the randomized efficacy part of the Phase 3 study and patients with non-cancer chronic pain included directly in the 52-week study. All patients had completed treatment by the end of the quarter and study results are expected mid-2019.

## CAM2029 – acromegaly and NET

CAM2029 is a ready-to-use long-acting subcutaneous depot of the active substance octreotide, a synthetic peptide analogue of the natural peptide hormone somatostatin and used for the treatment of acromegaly and neuroendocrine tumors (NET). CAM2029 is formulated with Camurus' patented FluidCrystal® injection depot technology and is being developed as a pre-filled syringe equipped with an automatic needle-stick prevention device. The current market leading somatostatin analog product Sandostatin® LAR® needs to be reconstituted in several steps before intramuscular injection by healthcare professionals. CAM2029 is designed for easy self-administration by patients themselves and thus offers the potential for improved patient convenience. In addition, CAM2029 provides higher bioavailability<sup>1</sup> of octreotide in comparison to Sandostatin® LAR®, which may improve treatment efficacy for patients not responding satisfactory to current therapies. CAM2029 has been evaluated in four clinical Phase 1/2 trials and has demonstrated positive results in a Phase 2 multicenter study in patients with acromegaly and NET, including well maintained or improved biochemical control in patients with acromegaly and symptom control in patients with functioning NET after switch from Sandostatin® LAR®.

### STATUS Q1

Preparations for the Phase 3 programs for CAM2029 for the treatment of acromegaly and neuroendocrine tumors continued. The pivotal Phase 3 trial for CAM2029 for the treatment of acromegaly is planned to start in the third quarter 2019, once approval of the study design has been received from the health authorities. In parallel, a Phase 3 trial for CAM2029 for the treatment of patients with NET is being planned.

Positive Phase 2 results for CAM2029 in two patient groups with acromegaly and NET, respectively, were published in *Cancer Chemotherapy and Pharmacology*<sup>2</sup>.

<sup>1</sup> Tiberg F, et al. *Br J Clin Pharmacol.* 2015;80:460-72

<sup>2</sup> Pavel M et al, *Cancer Chemother. and Pharmacol.*, 2018, available online

## CAM2043 – PAH

Pulmonary arterial hypertension (PAH) is a rare and severe progressive disease characterized by elevated blood pressure in the pulmonary arteries. Without therapeutic intervention, the disease progresses rapidly and the increased pulmonary vascular resistance and incremental strain on the right ventricle leads to heart failure and death, with a median survival of 3 years after diagnosis. Prostacyclin analogs, such as treprostinil, are known to be efficacious, and parenteral therapy with these is recommended by guidelines for patients with severe or rapidly progressing disease. However, parenteral delivery is associated with risks of serious bloodstream infections or with infusion site pain and reactions which can be intolerable.

CAM2043 is a long-acting treprostinil formulation, based on our FluidCrystal® injection depot technology, being developed as a patient-friendly treatment option for PAH. CAM2043 is a ready-to-use subcutaneous injection which is self-administered via a prefilled syringe as a small dose volume ( $\leq 1$  mL), allowing dose titration for efficacy and tolerability.

In an open-label Phase 1 study of single and repeated dosing of CAM2043, study results demonstrated a dose-proportional treprostinil plasma exposure and release profile suitable for weekly, or less frequent, dosing. The tolerability of CAM2043 was generally acceptable with no observations of unexpected or serious adverse events. Injection site reactions were acceptable and resolved over time.

### STATUS Q1

Further clinical development of CAM2043 is now being prepared and a Phase 2 study in PAH patients, assessing efficacy, pharmacokinetics, safety and tolerability is planned to start in H2 2019.

## Other pipeline projects

Several new product candidates, selected with support of market analyses, are being evaluated in pharmaceutical and pre-clinical studies. The projects comprise formulation optimization regarding release of the active substance and stability, as well as pharmacological and toxicological properties defined by the target product profiles.

### STATUS Q1

#### CAM2032

The well-established hormone therapies for prostate cancer, based on gonadotropin releasing hormone agonists such as leuprolide, aim to reduce testosterone levels and thereby impede the growth of cancer cells. CAM2032 is a long-acting subcutaneous leuprolide depot for the treatment of prostate cancer. Based on the FluidCrystal® injection depot technology, CAM2032 is being developed for self-administration with a prefilled syringe as a small dose volume which does not require any reconstitution or temperature conditioning. Additional potential indications for CAM2032 include precocious puberty and endometriosis.

Discussions with potential development and commercialization partners are ongoing.

#### CAM2047, CAM2048 and CAM2058

Three new investigational products, based on our FluidCrystal® injection depot technology, are being developed for the treatment of chemotherapy induced nausea and vomiting (CAM2047), pain (CAM2048), and the combined treatment of postoperative pain, nausea and vomiting (CAM2058).

Results from a Phase 1 trial of CAM2047, CAM2048 and CAM2058 demonstrated that all products were well tolerated locally and systemically, with pharmacokinetic profiles meeting the target specifications for these product candidates. Planning of the registration program and analysis of market potential of these product candidates are ongoing.

### **CAM4072**

CAM4072 is a weekly formulation of the melanocortin 4 (MC4) agonist setmelanotide based on Camurus FluidCrystal® technology and is being developed by our partner Rhythm Pharmaceuticals for the treatment of rare genetic obesity disorders. The FDA has granted Rhythm's setmelanotide Breakthrough Therapy designation for the treatment of pro-opiomelanocortin (POMC) and leptin receptor (LepR) deficiency obesity and Orphan Drug Designation of treatment Prader-Willis Syndrome. Rhythm Pharmaceuticals has also received Priority Medicines (PRIME) designation for setmelanotide in Rare Genetic Disorders of Obesity from the EMA. Results from Phase 2 clinical trials of setmelanotide demonstrated significant reductions in compulsive overeating and body weight for patients with POMC and LepR deficiency obesity. Phase 3 clinical trials are ongoing for the daily setmelanotide formulation and for each of these indications while the long-acting formulation of setmelanotide, CAM4072, is being developed in parallel. Rhythm has successfully completed Phase 1 studies of single and repeat doses of CAM4072, and the development is now progressing with a Phase 2 study in the US.

### **Medical device – episil®**

episil® oral liquid is a medical device for the treatment of inflammatory and painful conditions in the oral cavity, currently being marketed in Europe, the US and other territories. The product provides fast pain relief and protection of sore and inflamed mucosal surfaces caused by, for example, oral mucositis, a common and serious side effect of cancer treatment. When in contact with the buccal membrane, episil® transforms into a thin protective layer of gel, offering effective pain relief for up to 8 hours. episil® oral liquid is based on our FluidCrystal® topical bioadhesive technology.

### **STATUS Q1**

During the period, our partner Solasia Pharma received market approval for episil in China and launch is being prepared for during the second or third quarter 2019. Market approval was also received by our partner BioImpact Pty in Australia and activities are ongoing to prepare for launch in Australia in mid-2019.



## **FINANCIAL OVERVIEW**

### **REVENUES**

Revenues during the quarter amounted to MSEK 18.5 (14.6), generated from license agreements, project activities and product sales. Product sales amounted to MSEK 11.0 (3.0). See also note 4.

### **OPERATING RESULT**

Marketing and distribution costs during the quarter, were MSEK -37.8 (-17.5). The increase compared to the same period last year is mainly attributable to the expansion of the commercial organization and the ongoing, and upcoming, launches of Buvidal® in Europe and Australia.

Administrative expenses was MSEK -6.9 (-5.0).

R&D costs, including depreciation and amortization of tangible and intangible assets were MSEK -54.6 (-37.5). The difference compared with the previous year is primarily related to preparations for the Phase 3 program for CAM2029 for the treatment of acromegaly.

The operating result for the quarter was MSEK -84.4 (-46.4).

### **FINANCIAL ITEMS AND TAX**

Tax was MSEK 17.2 (10.1) and is mainly attributable to deferred tax for the reported loss during the quarter.

The Swedish corporate tax rate for 2019 has been reduced to 21.4 percent.

### **RESULT FOR THE PERIOD**

The result for the period was MSEK -67.6 (-36.3), corresponding to earnings per share of SEK -1.50 (-0.97) before and after dilution.

1 January 2019 IFRS was implemented. This affected the result positively by MSEK 0.1.

### **CASH FLOW AND INVESTMENT**

Cash flow from operating activities, before change in working capital, was negative and amounted to MSEK -82.7 (-45.2).

Change in working capital affected the cash flow negatively by MSEK -7.8 (-1.8) and the difference compared to the same period last year is mainly attributable to an increase in inventory of Buvidal® to meet the increasing demand. Cash flow from investing activities was MSEK -4.8 (-0.7). From financing activities cash flow was MSEK 368.1 (0.0), generated from the rights issue completed 27 March 2019.

### **CASH**

The company's cash position as of 31 March 2019, was MSEK 406.6 (266.6). The difference compared to the previous year is mainly attributable to the operating result and the recently completed rights issue.

There were no outstanding loans as of 31 March 2019, and no loans have been taken up since.

### **EQUITY**

Consolidated equity as of 31 March 2019 was MSEK 561.2 (348.9). The difference compared to previous year is related to the company's result and the recently completed rights issue raising MSEK 376.3 in net proceeds.

### **ACQUISITIONS**

No acquisitions or divestments have occurred during the quarter.

### **CAMURUS' SHARE**

Camurus' share is listed on Nasdaq Stockholm.

At the end of the period, the total number of shares and votes was 47,976,858 (37,281,486) and the difference compared to previous year relates to the rights issue completed 27 March 2019.

Camurus has three subscription warrant programs active for the company's employees. During the quarter earnings after tax were negatively impacted by MSEK 1.5 related to the stay-on bonus the participants receive as part of the programs.

For information about number of warrants, potential dilution, subscription periods, strike prices and number of employees participating in the program, see Note 2.3.

### **PARENT COMPANY**

Revenues for the quarter amounted to MSEK 24.1 (17.3) and the result after tax was MSEK -73.6 (-36.4).

On 31 March 2019, equity in the Parent Company amounted to MSEK 533.5 (331.2).

Total assets at the end of the period was MSEK 646.1 (416.9) of which MSEK 394.4 (257.9) were cash and cash equivalents. The difference compared to previous year relate to the net result for the period and the recently completed rights issue.

## **OTHER DISCLOSURES**

### **PERSONNEL**

At the end of the period, Camurus had 103 (72) employees, of whom 62 (49) were within research and development, 32 (14) within business development and marketing and sales, while 8 (8) were within administration. The full-time equivalent employees during the quarter amounted to 92 (65).

### **SIGNIFICANT EVENTS AFTER THE PERIOD**

On 9 April 2019 Camurus' partner Braeburn initiated court proceedings to overturn the market exclusivity extending to 30 November 2020 and seek immediate market approval of Brixadi™ in the US.

### **FINANCIAL OUTLOOK 2019**

Camurus expects full-year revenue to be in the range of MSEK 130–160, excluding potential early milestone payments regarding Brixadi™ in the US. Product sales are expected to be in the range of MSEK 70–90. This outlook is based on current exchange rates in March 2019.

### **AUDIT**

This report has not been reviewed by the company's auditors.

### **FORWARD-LOOKING STATEMENTS**

This report includes forward-looking statements about expected and assumed future events, such as start of new development programs and regulatory approvals, and financial performance. These events are subject to risks, uncertainties and assumptions. This may cause actual results to differ materially from previous judgements.

### **ANNUAL GENERAL MEETING 2019**

Camurus Annual General Meeting will be held on Thursday 9 May at 17.00 CET, at Elite Hotel Ideon, Scheelevägen 27, Ideon Science Park, 223 63 Lund, Sweden.

### **FURHER INFORMATION**

For further information, please contact:  
Fredrik Tiberg, President & CEO  
Tel: +46 46 286 46 92, e-mail: [ir@camurus.com](mailto:ir@camurus.com)

Lund, Sweden, 9 May 2019  
Camurus AB  
Board of Directors

## FINANCIAL STATEMENTS

### Consolidated statement of comprehensive income

| KSEK                                       | Note | 2019<br>Jan-Mar | 2018<br>Jan-Mar | 2018<br>Jan-Dec |
|--------------------------------------------|------|-----------------|-----------------|-----------------|
| Net revenues                               | 4    | 18,494          | 14,639          | 49,321          |
| Cost of goods sold                         |      | -2,997          | -1,547          | -6,822          |
| <b>Gross profit</b>                        |      | <b>15,497</b>   | <b>13,092</b>   | <b>42,499</b>   |
| Marketing and distribution costs           |      | -37,779         | -17,502         | -100,884        |
| Administrative expenses                    |      | -6,934          | -4,999          | -21,999         |
| Research and development costs             |      | -54,647         | -37,502         | -207,664        |
| Other operating income                     |      | 191             | 28              | 830             |
| Other operating expenses                   |      | -758            | 454             | -               |
| <b>Operating result</b>                    |      | <b>-84,430</b>  | <b>-46,429</b>  | <b>-287,218</b> |
| Finance income                             |      | 22              | 40              | 175             |
| Finance expenses                           |      | -406            | -7              | -25             |
| <b>Net financial items</b>                 |      | <b>-384</b>     | <b>33</b>       | <b>150</b>      |
| <b>Result before tax</b>                   |      | <b>-84,814</b>  | <b>-46,396</b>  | <b>-287,068</b> |
| Income tax                                 | 9    | 17,188          | 10,127          | 52,392          |
| <b>Result for the period</b>               | 5    | <b>-67,626</b>  | <b>-36,269</b>  | <b>-234,676</b> |
| Exchange-rate differences                  |      | 259             | 148             | 46              |
| <b>Comprehensive income for the period</b> |      | <b>-67 367</b>  | <b>-36 121</b>  | <b>-234,630</b> |

Total comprehensive income is attributable to Parent Company shareholders.

## Earnings per share, based on earnings attributable to Parent Company shareholders for the period (in SEK per share)

| SEK                                     | 2019<br>Jan-Mar | 2018<br>Jan-Mar | 2018<br>Jan-Dec |
|-----------------------------------------|-----------------|-----------------|-----------------|
| Earnings per share before dilution, SEK | -1.50           | -0.97           | -6.20           |
| Earnings per share after dilution, SEK  | -1.50           | -0.97           | -6.20           |

Presently, the company has three subscription warrant programs active.  
For further information see page 7 Camurus' share, and Note 2.3.

## Consolidated balance sheet

| KSEK                                | Note | 2019-03-31     | 2018-03-31     | 2018-12-31     |
|-------------------------------------|------|----------------|----------------|----------------|
| <b>ASSETS</b>                       |      |                |                |                |
| <b>Fixed assets</b>                 |      |                |                |                |
| <b>Intangible assets</b>            |      |                |                |                |
| Capitalized development expenditure |      | 19,975         | 16,128         | 15,975         |
| <b>Tangible assets</b>              |      |                |                |                |
| Lease asset                         |      | 28,779         | –              | –              |
| Equipment                           |      | 10,592         | 10,053         | 10,899         |
| <b>Financial assets</b>             |      |                |                |                |
| Deferred tax receivables            | 3    | 196,284        | 125,296        | 170,955        |
| <b>Total fixed assets</b>           |      | <b>255,630</b> | <b>151,477</b> | <b>197,829</b> |
| <b>Current assets</b>               |      |                |                |                |
| <b>Inventories</b>                  |      |                |                |                |
| Finished goods                      |      | 10,078         | 1,893          | 4,700          |
| Raw materials                       |      | 6,109          | 471            | 5,130          |
| <b>Total inventories</b>            |      | <b>16,187</b>  | <b>2,364</b>   | <b>9,830</b>   |
| <b>Current receivables</b>          |      |                |                |                |
| Trade receivables                   |      | 5,452          | 1,270          | 2,280          |
| Other receivables                   |      | 7,505          | 4,703          | 9,604          |
| Prepayments and accrued income      |      | 12,010         | 9,425          | 10,804         |
| <b>Total current receivables</b>    | 6    | <b>24,967</b>  | <b>15,398</b>  | <b>22,688</b>  |
| Cash and cash equivalents           |      | 406,622        | 266,633        | 134,377        |
| <b>Total current assets</b>         |      | <b>447,776</b> | <b>284,395</b> | <b>166,895</b> |
| <b>TOTAL ASSETS</b>                 |      | <b>703,406</b> | <b>435,872</b> | <b>364,724</b> |

| KSEK                                                             | Note | 2019-03-31     | 2018-03-31     | 2018-12-31     |
|------------------------------------------------------------------|------|----------------|----------------|----------------|
| <b>EQUITY</b>                                                    |      |                |                |                |
| <b>Equity attributable to parent company shareholder</b>         |      |                |                |                |
| Share capital                                                    |      | 1,199          | 932            | 960            |
| Other contributed capital                                        |      | 1,120,183      | 642,175        | 744,140        |
| Retained earnings, including comprehensive result for the period |      | -560,172       | -294,228       | -492,776       |
| <b>Total equity</b>                                              | 10   | <b>561,210</b> | <b>348,879</b> | <b>252,324</b> |
| <b>LIABILITIES</b>                                               |      |                |                |                |
| <b>Long-term liabilities</b>                                     |      |                |                |                |
| Lease liabilities                                                |      | 24,456         | –              | –              |
| <b>Total long-term liabilities</b>                               |      | <b>24,456</b>  | <b>–</b>       | <b>–</b>       |
| <b>Short-term liabilities</b>                                    |      |                |                |                |
| Trade payables                                                   |      | 16,837         | 12,579         | 35,781         |
| Lease liability                                                  |      | 3,399          | –              | –              |
| Income taxes                                                     |      | 2,636          | 718            | 1,708          |
| Other liabilities                                                |      | 11,368         | 7,059          | 3,549          |
| Accrued expenses and deferred income                             |      | 83,500         | 66,637         | 71,362         |
| <b>Total short-term liabilities</b>                              |      | <b>117,740</b> | <b>86,993</b>  | <b>112,400</b> |
| <b>TOTAL EQUITY AND LIABILITIES</b>                              |      | <b>703,406</b> | <b>435,872</b> | <b>364,724</b> |



## Consolidated statement of changes in equity

| KSEK                                               | Note | Share capital | Other contributed capital | Retained earnings, including result for the period | Total equity   |
|----------------------------------------------------|------|---------------|---------------------------|----------------------------------------------------|----------------|
| <b>Opening balance 1 January 2018</b>              |      | <b>932</b>    | <b>642,175</b>            | <b>-258,107</b>                                    | <b>385,000</b> |
| Comprehensive income for the period                |      |               |                           | -36,121                                            | -36,121        |
| <b>Transactions with shareholders</b>              |      |               |                           |                                                    |                |
| Warrants issued                                    |      | -             | -                         | -                                                  | -              |
| <b>Closing balance 31 March 2018</b>               |      | <b>932</b>    | <b>642,175</b>            | <b>-294,228</b>                                    | <b>348,879</b> |
| <b>Opening balance 1 January 2018</b>              |      | <b>932</b>    | <b>642,175</b>            | <b>-258,107</b>                                    | <b>385,000</b> |
| Comprehensive income for the period                |      |               |                           | -234,630                                           | -234,630       |
| <b>Transactions with shareholders</b>              |      |               |                           |                                                    |                |
| Directed share issue                               |      | 28            | 102,272                   | -                                                  | 102,300        |
| Issuance costs, net after deferred tax             |      | -             | -7,456                    | -                                                  | -7,456         |
| Warrants issued                                    |      | -             | 7,110                     | -                                                  | 7,110          |
| <b>Closing balance 31 December 2018</b>            |      | <b>960</b>    | <b>744,101</b>            | <b>-492,737</b>                                    | <b>252,324</b> |
| <b>Opening balance 1 January 2019</b>              |      | <b>960</b>    | <b>744,101</b>            | <b>-492,737</b>                                    | <b>252,324</b> |
| Comprehensive income for the period                |      |               |                           | -67,367                                            | -67,367        |
| <b>Transactions with shareholders</b>              |      |               |                           |                                                    |                |
| Directed share issue                               |      | 239           | 402,766                   | -                                                  | 403,005        |
| Preliminary issuance costs, net after deferred tax |      | -             | -26,752                   | -                                                  | -26,752        |
| Warrants issued                                    |      | -             | -                         | -                                                  | -              |
| <b>Closing balance 31 March 2019</b>               | 10   | <b>1,199</b>  | <b>1,120,115</b>          | <b>-560,104</b>                                    | <b>561,210</b> |

## Consolidated statement of cash flow

| KSEK                                                     | Note | 2019<br>Jan-Mar | 2018<br>Jan-Mar | 2018<br>Jan-Dec |
|----------------------------------------------------------|------|-----------------|-----------------|-----------------|
| <b>Operating activities</b>                              |      |                 |                 |                 |
| Operating result before financial items                  |      | -84,430         | -46,429         | -287,218        |
| Adjustment for non-cash items                            | 8    | 2,156           | 1,196           | 4,450           |
| Interest received                                        |      | 22              | 40              | 175             |
| Interest paid                                            |      | -406            | -7              | -25             |
| Income taxes paid                                        |      | 7               | -               | -272            |
|                                                          |      | <b>-82,651</b>  | <b>-45,200</b>  | <b>-282,890</b> |
| Increase/decrease in inventories                         |      | -6,357          | 1,189           | -6,277          |
| Increase/decrease in trade receivables                   |      | -3,172          | 4,511           | 3,501           |
| Increase/decrease in other current receivables           |      | -211            | -3,604          | -9,884          |
| Increase/decrease in trade payables                      |      | -18,944         | -2,507          | 20,695          |
| Increase/decrease in other current operating liabilities |      | 20,885          | -1,434          | 771             |
| <b>Cash flow from changes in working capital</b>         |      | <b>-7,799</b>   | <b>-1,845</b>   | <b>8,806</b>    |
| <b>Cash flow from operating activities</b>               |      | <b>-90,450</b>  | <b>-47,045</b>  | <b>-274,084</b> |
| <b>Investing activities</b>                              |      |                 |                 |                 |
| Acquisition of intangible assets                         |      | -4,525          | -               | -1,404          |
| Acquisition of tangible assets                           |      | -318            | -666            | -3,357          |
| <b>Cash flow from investing activities</b>               |      | <b>-4,843</b>   | <b>-666</b>     | <b>-4,761</b>   |
| <b>Financing activities</b>                              |      |                 |                 |                 |
| Increase/decrease in long-term liabilities               |      | -821            | -               | -               |
| Directed share issue                                     |      | 368,970         | -               | 92,741          |
| Warrants issued                                          |      | -               | -               | 7,110           |
| <b>Cash flow from financing activities</b>               |      | <b>368,149</b>  | <b>-</b>        | <b>99,851</b>   |
| <b>Net cash flow for the period</b>                      |      | <b>272,856</b>  | <b>-47,711</b>  | <b>-178,994</b> |
| Cash and cash equivalents at beginning of period         |      | 134,377         | 314,524         | 314,524         |
| Translation difference in cash flow and liquid assets    |      | -611            | -180            | -1,153          |
| <b>Cash and cash equivalents at the end of period</b>    |      | <b>406,622</b>  | <b>266,633</b>  | <b>134,377</b>  |

## Income statement – Parent Company

| KSEK                                           | Note | 2019<br>Jan-Mar | 2018<br>Jan-Mar | 2018<br>Jan-Dec |
|------------------------------------------------|------|-----------------|-----------------|-----------------|
| Net sales                                      |      | 24,057          | 17,265          | 67,111          |
| Cost of goods sold                             |      | -2,997          | -1,547          | -6,822          |
| <b>Gross profit</b>                            |      | <b>21,060</b>   | <b>15,718</b>   | <b>60,289</b>   |
| Marketing and distribution costs <sup>1)</sup> |      | -53,768         | -10,273         | -46,970         |
| Administrative expenses <sup>1)</sup>          |      | -1,445          | -15,695         | -99,890         |
| Research and development costs                 |      | -57,669         | -36,967         | -206,709        |
| Other operating income                         |      | 14              | –               | 838             |
| Other operating expenses                       |      | -466            | 579             | –               |
| <b>Operating result</b>                        |      | <b>-92,274</b>  | <b>-46,638</b>  | <b>-292,442</b> |
| Interest income and similar items              |      | 22              | 40              | 175             |
| Interest expense and similar items             |      | -12             | -7              | -24             |
| <b>Result after financial items</b>            |      | <b>-92,264</b>  | <b>-46,605</b>  | <b>-292,291</b> |
| <b>Result before tax</b>                       |      | <b>-92,264</b>  | <b>-46,605</b>  | <b>-292,291</b> |
| Tax on profit for the period                   | 9    | 18,622          | 10,183          | 53,527          |
| <b>Result for the period</b>                   |      | <b>-73,642</b>  | <b>-36,422</b>  | <b>-238,764</b> |

<sup>1)</sup>During 2018 group internal recharges were included in the function administrative expenses. As of 2019 these costs have been reclassified as marketing and distribution costs. If this reclassification had not been done administrative expenses would have amounted to KSEK -41,762 and marketing and distribution costs to KSEK -13,451. The increase in cost compared to previous year, is mainly related to group internal recharges regarding the commercial organization.

Total comprehensive income is the same as profit/loss for the period, as the parent company contains no items that are recognized under other comprehensive income.

## Balance sheet – Parent Company

| KSEK                             | Note | 2019-03-31     | 2018-03-31     | 2018-12-31     |
|----------------------------------|------|----------------|----------------|----------------|
| <b>ASSETS</b>                    |      |                |                |                |
| <b>Fixed assets</b>              |      |                |                |                |
| <b>Tangible fixed assets</b>     |      |                |                |                |
| Equipment                        |      | 10,387         | 9,878          | 10,689         |
| <b>Financial fixed assets</b>    |      |                |                |                |
| Interest in Group companies      |      | 1,800          | 1,545          | 1,800          |
| Deferred tax assets              |      | 200,962        | 129,610        | 175,056        |
| <b>Total fixed assets</b>        |      | <b>213,149</b> | <b>141,033</b> | <b>187,545</b> |
| <b>Current assets</b>            |      |                |                |                |
| <b>Inventories</b>               |      |                |                |                |
| Finished goods                   |      | 10,078         | 1,893          | 4,700          |
| Raw materials                    |      | 6,109          | 471            | 5,130          |
| <b>Total inventories</b>         |      | <b>16,187</b>  | <b>2,364</b>   | <b>9,830</b>   |
| <b>Current receivables</b>       |      |                |                |                |
| Trade receiv                     |      | 5,452          | 1,270          | 2,280          |
| Other receivables                |      | 3,760          | 5,244          | 7,219          |
| Prepayments and accrued income   |      | 13,107         | 9,130          | 10,679         |
| <b>Total current receivables</b> |      | <b>22,319</b>  | <b>15,644</b>  | <b>20,178</b>  |
| Cash and bank deposits           |      | 394,446        | 257,850        | 123,858        |
| <b>Total current assets</b>      |      | <b>432,952</b> | <b>275,858</b> | <b>153,866</b> |
| <b>TOTAL ASSETS</b>              |      | <b>646,101</b> | <b>416,890</b> | <b>341,411</b> |

| KSEK                                        | Note | 2019-03-31     | 2018-03-31     | 2018-12-31     |
|---------------------------------------------|------|----------------|----------------|----------------|
| <b>EQUITY AND LIABILITES</b>                |      |                |                |                |
| <b>Restricted equity</b>                    |      |                |                |                |
| Restricted equity (47,976,858 shares)       |      | 1,199          | 932            | 960            |
| Statutory reserve                           |      | 11,327         | 11,327         | 11,327         |
| <b>Total restricted equity</b>              |      | <b>12,526</b>  | <b>12,259</b>  | <b>12,287</b>  |
| <b>Unrestricted equity</b>                  |      |                |                |                |
| Retained earnings                           |      | -491,923       | -253,159       | -253,159       |
| Share premium reserve                       |      | 1,086,501      | 608,560        | 710,487        |
| Result for the period                       |      | -73,642        | -36,422        | -238,764       |
| <b>Total unrestricted equity</b>            |      | <b>520,936</b> | <b>318,979</b> | <b>218,564</b> |
| <b>TOTAL EQUITY</b>                         |      | <b>533,462</b> | <b>331,238</b> | <b>230,851</b> |
| <b>LIABILITIES</b>                          |      |                |                |                |
| <b>Untaxed reserves</b>                     |      |                |                |                |
| Depreciation/amortization in excess of plan |      | 3,486          | 3,486          | 3,486          |
| <b>Total untaxed reserves</b>               |      | <b>3,486</b>   | <b>3,486</b>   | <b>3,486</b>   |
| <b>Long-term liabilities</b>                |      |                |                |                |
| Liability to subsidiaries                   |      | 572            | 571            | 572            |
| <b>Total long-term liabilities</b>          |      | <b>572</b>     | <b>571</b>     | <b>572</b>     |
| <b>Short-term liabilities</b>               |      |                |                |                |
| Liabilities to Group companies              |      | 9,296          | 1,362          | 9,065          |
| Trade payables                              |      | 15,119         | 12,372         | 32,650         |
| Other liabilities                           |      | 8,296          | 5,466          | 2,355          |
| Accrued expenses and deferred income        |      | 75,870         | 62,395         | 62,432         |
| <b>Total short-term liabilities</b>         |      | <b>108,581</b> | <b>81,595</b>  | <b>106,502</b> |
| <b>TOTAL EQUITY AND LIABILITY</b>           |      | <b>646,101</b> | <b>416,890</b> | <b>341,411</b> |

## KEY FIGURES AND DEFINITIONS

| MSEK                                            | 2019<br>Jan-Mar | 2018<br>Jan-Mar | 2018<br>Jan-Dec |
|-------------------------------------------------|-----------------|-----------------|-----------------|
| Net sales                                       | 18.5            | 14.6            | 49.3            |
| Operating result                                | -84.4           | -46.4           | -287.2          |
| Result for the period                           | -67.6           | -36.3           | -234.7          |
| Cash flow from operating activities             | -90.5           | -47.0           | -274.1          |
| Cash and cash equivalents                       | 406.6           | 266.6           | 134.4           |
| Equity                                          | 561.2           | 348.9           | 252.3           |
| Equity ratio, percent                           | 80%             | 80%             | 69%             |
| Total assets                                    | 703.4           | 435.9           | 364.7           |
| Average number of shares, before dilution       | 45,098,246      | 37,281,486      | 37,842,034      |
| Average number of shares, after dilution*)      | 46,723,878      | 38,344,718      | 39,231,356      |
| Earnings per share before dilution, SEK         | -1.50           | -0.97           | -6.20           |
| Earnings per share after dilution, SEK*)        | -1.50           | -0.97           | -6.20           |
| Equity per share before dilution, SEK           | 12.44           | 9.36            | 6.67            |
| Equity per share after dilution, SEK*)          | 12.01           | 9.10            | 6.43            |
| Number of employees at the end of period        | 103             | 72              | 94              |
| Number of employees in R&D at the end of period | 62              | 49              | 58              |
| R&D costs as a percentage of operating expenses | 55%             | 63%             | 63%             |

\*) The dilution effect is calculated according to IAS 33

### Cash and cash equivalents

Cash and cash bank balances

### Equity ratio, %

Equity divided by total capital

### Average number of shares, before dilution

Weighted average number of shares before adjustment for dilution effect of net shares

### Average number of shares, after dilution

Weighted average number of shares adjustment for the dilution effect of new shares

### Earnings per share before dilution, SEK

Result divided by the weighted average number of shares outstanding before dilution

### Earnings per share after dilution, SEK

Result divided by the weighted average number of shares outstanding after dilution

### Equity per share before dilution, SEK

Equity divided by the weighted number of shares at the end of the period before dilution

### Equity per share after dilution, SEK

Equity divided by the weighted number of shares at the end of the period after dilution

### R&D costs as percentage of operating expenses

Research and development costs divided by operating expenses (marketing and distribution costs, administrative expenses and research and development costs)



## NOTES

### Note 1 | General information

Camurus AB, Corp. ID no. 556667-9105 is the parent company of the Camurus Group. Camurus AB's registered office is based in Lund, Sweden, at Ideon Science Park, 223 70 Lund. Camurus AB Group's interim report for the first quarter 2019 was approved for publication by the Board of Directors and the chief executive officer.

All amounts are stated in SEK thousand (KSEK), unless otherwise indicated. Figures in brackets refer to the year-earlier period.

### Note 2 | Summary of key accounting policies

The consolidated financial statements for the Camurus AB Group ("Camurus") have been prepared in accordance with International Financial Reporting Standards (IFRS) as adopted by the EU, as well as the Swedish Financial Reporting Board's Recommendation RFR 1 Supplementary Accounting Rules for Groups, and the Swedish Annual Account Act.

This interim report has been drawn up in accordance with IAS 34, Interim Financial Reporting, the Swedish Annual Accounts Act and RFR 1 Supplementary Accounting Rules the Groups.

The parent company statements have been prepared in accordance with the Annual Accounts Act and recommendation RFR 2 Accounting for legal entities from the Swedish Financial Reporting Board. The application of RFR 2 means

that the parent company in the interim report for the legal entity shall apply all EU-approved IFRS standards and statements as far as possible within the framework of the Annual Accounts Act, the Pension Obligations Vesting Act (Tryggandelagen) and taking into consideration the relationship between accounting and taxation. The parent company's accounting policies are the same for the Group, unless otherwise stated in Note 2.2.

The most important accounting policies that are applied in the preparation of these consolidated financial statements are detailed below and are the same and consistent with those used in the preparation of Annual Report 2018, see [camurus.com/Investors/Financial Reports](http://camurus.com/Investors/Financial%20Reports). In addition, the new standard IFRS 16 Leases came into force 1 January 2019 replacing IAS 17 Leases.

At the transition to IFRS 16, Camurus have chosen to perform the transition in line with the Cumulative catch-up approach and have applied the practical approach to not restate any comparative information. Right-of-use assets have been determined as an amount equal to the lease liabilities as identified at initial application. The lease portfolio includes only a few lease contracts and covers mainly operational leases for offices, laboratories and company cars. For contracts concerning premises, Camurus has determined a contract period, taken into account how notice and extension clauses have been applied previously, the premise's importance to the Company's operations and R&D, any planned or already implemented investments to the leased facility as well as market situation for premises. A discount rate has been applied per asset classes Buildings and vehicles. Lease contracts shorter than 12 months or ending within 12 months at the date of application are considered short-term and hence not recognized as lease liability

or right-of-use asset. Furthermore, low value contracts (with a value as new below USD 5,000) are also excluded from being recognized as lease liability or right-of-use asset.

As an effect of the transition, the Groups' total assets at the transition date 1 January 2019 have increased by MSEK 29.8, representing 4.2% of the balance sheet. The Group's financial liabilities have increased by MSEK 28.7, representing 4.1% of the balance sheet. For information about change in opening balance 1 January 2019, see table on next side.

During the quarter, IFRS 16 impact on the operating profit was MSEK 1.0 in increased depreciations and MSEK 1.2 in decreased other operating expenses. Thus, no material impact on operating profit and EPS.

## Change in opening balance 1 January 2019 due to transition to IFRS 16 Leasing

| KSEK                                    | 2018-12-31     | IFRS 16<br>justering | 2019-01-01     |
|-----------------------------------------|----------------|----------------------|----------------|
| <b>ASSETS</b>                           |                |                      |                |
| <b>Fixed assets</b>                     |                |                      |                |
| Intangible assets                       | 15,975         | –                    | 15,975         |
| Tangible assets                         | 10,899         | 29,780               | 40,679         |
| Financial assets                        | 170,955        | –                    | 170,955        |
| <b>Total fixed assets</b>               | <b>197,829</b> | <b>29,780</b>        | <b>227,609</b> |
| <b>Current assets</b>                   |                |                      |                |
| Current assets                          | 166,895        | -1,104               | 165,791        |
| <b>Total current assets</b>             | <b>166,895</b> | <b>-1,104</b>        | <b>165,791</b> |
| <b>Total assets</b>                     | <b>364,724</b> | <b>28,676</b>        | <b>393,400</b> |
| <b>EQUITY AND LIABILITIES</b>           |                |                      |                |
| <b>Equity</b>                           | <b>252,324</b> | <b>–</b>             | <b>252,324</b> |
| <b>Long-term liabilities</b>            |                |                      |                |
| Lease liabilities                       | –              | 25,277               | 25,277         |
| Other liabilities, non-interest bearing | –              | –                    | –              |
| <b>Total long-term liabilities</b>      | <b>–</b>       | <b>25,277</b>        | <b>25,277</b>  |
| <b>Short-term liabilities</b>           |                |                      |                |
| Lease liabilities                       | –              | 3,399                | 3,399          |
| Other liabilities, non-interest bearing | 112,400        | –                    | 112,400        |
| <b>Total short-term liabilities</b>     | <b>112,400</b> | <b>3,399</b>         | <b>115,799</b> |
| <b>TOTAL EQUITY AND LIABILITIES</b>     | <b>364,724</b> | <b>28,676</b>        | <b>393,400</b> |

## 2.1 BASIS OF PREPARATION OF REPORTS

### 2.1.1 Changes to accounting policies and disclosures

New or revised IFRS standards that have come into force have not had any material impact on the Group.

### 2.2 PARENT COMPANY'S ACCOUNTING POLICIES

The parent company applies accounting policies that differ from those of the Group in the cases stated below.

#### Internally generated intangible assets

All expenses that relate to the development of internally generated intangible assets are recognized as expenses as they arise.

#### Interest in subsidiary

Interests in subsidiaries are reported at cost, less any impairment losses. The cost includes acquisition-related expenses and any additional considerations. When there is an indication that interests in subsidiaries have decreased in value, a calculation is made of the recoverable amount. If this amount is lower than the reported amount, an impairment is carried out. Impairment losses are recognized under the item "Result from interest in Group companies".

#### Group contributions

Group contributions paid by the parent company to subsidiaries and Group contributions received from subsidiaries by the parent company are recognized as appropriations.

#### Financial instruments

IFRS 9 "Financial instruments" addresses the classification, measurement and recognition of financial assets and liabilities and is applied with the exceptions that RFR2 allows, ie at amortized cost.

## NOTES

### 2.3 SHARE-BASED PAYMENT

Camurus has three long-term incentive programs active for the company's employees. The warrants are valued by an independent institute in accordance with Black&Scholes model and are acquired by the participants at market value. As part of the program, the participants receive a threepiece stay-on bonus from the company in form of gross salary additions equivalent to the amount paid by the participant for the subscription warrants. As the stay-on bonus is conditional on continued employment, costs including social security fee, are based on how much has been earned, and are expensed over the vesting period. Expenses are recognized as personnel cost in the income statement. The programs were adopted by the Annual General Meeting in 2016, 2017 and 2018. Below a summary of the programs:

| <b>Program</b> | <b>Number of subscribed warrants<sup>1)</sup></b> | <b>Potential dilution of the subscribed warrants<sup>1)</sup></b> | <b>Subscription period</b>  | <b>Strike price SEK, for subscription of shares upon exercise<sup>1)</sup></b> | <b>Number of employees participating in the program</b> |
|----------------|---------------------------------------------------|-------------------------------------------------------------------|-----------------------------|--------------------------------------------------------------------------------|---------------------------------------------------------|
| TO2016/2019    | 438,175                                           | 0.91%                                                             | 15 May 2019-<br>15 Dec 2019 | 91.81                                                                          | 47                                                      |
| TO2017/2020    | 715,816                                           | 1.49%                                                             | 15 May 2020-<br>15 Dec 2020 | 153.91                                                                         | 44                                                      |
| TO2018/2021    | 610,950                                           | 1.27%                                                             | 15 May 2021-<br>15 Dec 2021 | 133.39                                                                         | 47                                                      |
| <b>Total</b>   | <b>1,764,941</b>                                  | <b>3.68%</b>                                                      |                             |                                                                                |                                                         |

1) After recalculation, which according to the terms of the programs was called for in connection with the rights issue carried out on 27 March 2019.

### Note 3 | Significant risks and uncertainties

The company management makes estimates and assumptions about the future. Such estimates can deviate considerably from the actual outcome, since they are based on various assumptions and experiences.

The estimates and assumptions that may lead to the risk of significant adjustments to reported amounts for assets and liabilities relate mainly to measurement and allocation of revenues and costs in connection with licensing agreements and deferred tax receivables.

Risks in ongoing development projects comprise technical and manufacturing related risks (including products failing to meet set specifications post manufacturing), safety and effect-related risks that can arise in clinical trials, regulatory risks relating to non-approval or delays of clinical trial applications and market approvals, and commercial risks relating to the sale of proprietary and competing products and their development on the market, as well as IP risks relating to approval of patent applications and patent protection. In addition, there are risks relating to the development, strategy and management decisions of Camurus' partners. Camurus pursues operations and its business on the international market and the company is therefore exposed to current risks, since revenues and costs arise in different currencies, mainly SEK, EUR, GBP and USD. The Group reports a deferred tax asset

of MSEK 196.3 as of 31 March 2019. The deferred tax asset is calculated on the basis that Camurus AB's entire losses carried forward will be utilized against taxable surpluses in the future. The basic circumstance leading the company to make this assessment is that the company, for the development of new drug candidates, utilizes its own proprietary and regulatory validated long-acting FluidCrystal® injection depot. By combining this technology with already existing active drug substances whose efficacy and safety profile previously has been documented, new proprietary drugs with improved properties and treatment results can be developed in shorter time, at a lower cost and risk compared to the development of completely new drugs. Accounting for deferred tax assets according to IFRS requires that it is probable that taxable surpluses will be generated in the future which the losses carried forward can be used against. In addition, a company that has reported losses in recent periods must be able to demonstrate convincing factors that taxable profits will be generated. The progress made in the development of CAM2038 for the treatment of opioid dependence (Phase 3 studies and regulatory approvals) and success in previous projects using FluidCrystal® injection depot is what convincingly suggests that the company will be able to utilize its losses carried forward. The fact that the Company has reported losses is natural in an industry where it takes considerable time to develop and launch new products, even when these are based on a proven technology and substances that are well-proven. We see the

European Commission approval of Buvidal® for treatment of opioid dependence on November 22, 2018, Australian TGA's approval on November 28, 2018, and the FDA's tentative approval for Brixadi™, weekly and monthly depot on December 21, 2018 (meaning that Brixadi™ has met all regulatory requirements regarding clinical and preclinical safety, treatment effect and quality, but that a final approval of Brixadi™ (monthly depot) is dependent on the expiry of an exclusivity period granted by the FDA to Sublocade™; which may not last longer than until November 2020), as further validation of our formulation technology FluidCrystal®, and are events that confirm the likelihood assessments made by the Company when calculating the amount of the deferred tax asset. Future revenues will be generated through entered partnerships for the markets where Camurus outlicensed FluidCrystal® and/or product candidates or products such as Buvidal®, and from Camurus' own sales organization for the markets where Camurus have own commercialization capabilities to sell pharmaceutical products. Losses carried forward are only reported in Sweden and without any due dates based on current tax legislation in Sweden.

A more detailed description of the Group's risk exposure is included in Camurus Annual Report 2018 (The Director's Report).

The Board of Directors has not changed its outlook on future developments in relations to their outlook published in the annual report for 2018.

## Note 4 | Segment information

The highest executive decision maker is the function responsible for allocating resources and assessing the operating segments results. In the Group this function is identified as the CEO based on the information he manages. As the operations in the Group, i.e. the development of pharmaceutical products based on Camurus' technology platform, is organized as an integrated unit, with similar risks and opportunities for the products and services produced, the entire Group's business constitutes one operating segment. The operating segment is monitored in a manner consistent with the internal reporting provided to the chief operating decision maker. In the internal reporting to the CEO, only one segment is used.

### Group-wide information

To follow is a breakdown of revenues from all products and services.

| KSEK                                            | 2019<br>Jan-Mar | 2018<br>Jan-Mar | 2018<br>Jan-Dec |
|-------------------------------------------------|-----------------|-----------------|-----------------|
| Sales of development related goods and services | 1,661           | 3,831           | 11,378          |
| License and milestone revenues                  | 5,865           | 7,840           | 26,626          |
| Product sales*)                                 | 10,968          | 2,968           | 11,317          |
| <b>Total</b>                                    | <b>18,494</b>   | <b>14,639</b>   | <b>49,321</b>   |

\*) Reelating to Buvidal® and episil®.

Revenues from external customers are allocated by country, based on where the customers are located.

| KSEK                           | 2019<br>Jan-Mar | 2018<br>Jan-Mar | 2018<br>Jan-Dec |
|--------------------------------|-----------------|-----------------|-----------------|
| Europe                         | 11,313          | 532             | 3,687           |
| (of which Sweden)              | (259)           | (121)           | (327)           |
| North America                  | 1,309           | 11,310          | 35,562          |
| Asia including Oceania         | 5,872           | 2,797           | 9,763           |
| Other geographical territories | –               | –               | 309             |
| <b>Total</b>                   | <b>18,494</b>   | <b>14,639</b>   | <b>49,321</b>   |

Revenues during the quarter of approximately MSEK 10.5 (8.4) relate to one single external customer.



## Note 5 | Earnings per share

### a) Before dilution

Earnings per share before dilution is calculated by dividing the result attributable to shareholders of the parent company by a weighted average number of ordinary shares outstanding during the period. During the period, no shares held as treasury shares by the parent company have been repurchased.

### b) After dilution

In order to calculate earnings per share after dilution, the number of existing ordinary shares is adjusted for the dilutive effect of the weighted average number of outstanding ordinary shares. The parent company has one category of ordinary shares with anticipated dilution effect in the form of warrants. For warrants, a calculation is made of the number of shares that could have been purchased at fair value (calculated as the average market price for the year for the parent company's shares), at an amount corresponding to the monetary value of the subscription rights linked to outstanding warrants. The number of shares calculated as above are compared to the number of shares that would have been issued assuming the warrants are exercised.

| KSEK                                                                      | 2019<br>Jan-Mar | 2018<br>Jan-Mar | 2018<br>Jan-Dec |
|---------------------------------------------------------------------------|-----------------|-----------------|-----------------|
| Result attributable to parent company shareholders                        | -67,626         | -36,269         | -234,676        |
| <b>Total</b>                                                              | <b>-67,626</b>  | <b>-36,269</b>  | <b>-234,676</b> |
| <b>Weighted average number of ordinary shares outstanding (thousands)</b> | <b>45,098</b>   | <b>37,281</b>   | <b>37,842</b>   |

| KSEK                                                                                                              | 2019<br>Jan-Mar | 2018<br>Jan-Mar | 2018<br>Jan-Dec |
|-------------------------------------------------------------------------------------------------------------------|-----------------|-----------------|-----------------|
| Result attributable to parent company shareholders                                                                | -67,626         | -36,269         | -234,676        |
| <b>Total</b>                                                                                                      | <b>-67,626</b>  | <b>-36,269</b>  | <b>-234,676</b> |
| <b>Weighted average number of ordinary shares outstanding (thousands)</b>                                         | <b>45,098</b>   | <b>37,281</b>   | <b>37,842</b>   |
| Adjustments:                                                                                                      |                 |                 |                 |
| – Warrants (thousands)                                                                                            | 1,626           | 1,063           | 1,389           |
| – Share issues (thousands)                                                                                        | –               | –               | –               |
| <b>Weighted average number of ordinary shares in calculation of earnings per share after dilution (thousands)</b> | <b>46,724</b>   | <b>38,344</b>   | <b>39,231</b>   |

## Note 6 | Financial instruments – Fair value of financial assets and liability measured at amortized cost

All of the Group's financial instruments that are measured at amortized cost are short-term and expire within one year. The fair value of these instruments is deemed to correspond to their reported amounts, since discounting effects are minimal.

## Note 7 | Related party transaction

There were no related party transactions outside of the Camurus group during the period.

No receivables or liabilities existed as of 31 March 2019.

| Carrying amount, KSEK            | 2019-03-31     | 2018-03-31     | 2018-12-31     |
|----------------------------------|----------------|----------------|----------------|
| <b>Loans and receivables</b>     |                |                |                |
| Trade receivables                | 5,452          | 1,270          | 2,280          |
| Receivables from Group companies | –              | –              | –              |
| Other receivables                | 180            | –              | –              |
| Cash and cash equivalents        | 406,622        | 266,633        | 134,377        |
| <b>Total</b>                     | <b>412,254</b> | <b>267,903</b> | <b>136,657</b> |
| <b>Other liabilities</b>         |                |                |                |
| Other financial liabilities      | –              | –              | –              |
| Liabilities to Group companies   | –              | –              | –              |
| Trade payables                   | 16,837         | 12,579         | 35,781         |
| Other current liabilities        | 190            | 191            | 190            |
| <b>Total</b>                     | <b>17,027</b>  | <b>12,770</b>  | <b>35,971</b>  |

## NOTES

### Note 8 | Other non-cash items

Adjustment for non-cash items:

| KSEK         | 2019<br>Jan-Mar | 2018<br>Jan-Mar | 2018<br>Jan-Dec |
|--------------|-----------------|-----------------|-----------------|
| Depreciation | 2,156           | 1,048           | 4,450           |
| <b>Total</b> | <b>2,156</b>    | <b>1,048</b>    | <b>4,450</b>    |

### Note 9 | Tax

Tax for the quarter amounted to MSEK 17.2 (10.1), primary attributable to the negative result.

### Note 10 | Equity

The change in equity for the quarter is mainly attributable to the loss during the period and the recently completed rights issue.

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*This information is information that Camurus AB is obliged to make public pursuant to the EU Market Abuse Regulation and the Swedish Securities Markets Act. The information was submitted for publication, through the agency of the chief executive officer, 1.00 PM (CET) on 9 May 2019.*

**camurus**<sup>®</sup>

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